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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,160	02/06/2002	Dennis Klinman	4239-61997	9731

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EXAMINER	
NGUYEN, DAVE TRONG	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/068,160	KLINMAN ET AL.	
	Examiner	Art Unit	
	Dave T Nguyen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8,12-22 and 60-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,12-22 and 60-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 February 2002* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-7, 9-10, and 11 have been canceled, claims 60-66 have been added, claims 8, 12-14, 16-19, 21, 22 have been amended by the amendment filed April 19, 2004.

Claims 8, 12-22, and 60-66 are pending. The examiner acknowledges the interview with applicant on March 9, 2004. However, a new ground of rejection is applicable as set forth below.

The cross-reference information is objected because the cross-reference information does not set forth the exact relationship between Application 09/958,713 and PCT/US00/09839. If the '713 is a 371 application of the PCT application, then such relationship must be disclosed in order obviate the priority information, should this application be issued as a US patent.

The brief description of drawings is objected because the brief description does not contain any reference to Figures 4A-4F, and 5A-5C.

The application is objected under Sequence Rules 1.821 because the application does not conform to the requirements of 37 CFR 1.821 because the specification and claims contain DNA sequences, *e.g.*, SEQ ID NO: 138, for which there is neither a computer readable file nor a paper copy of the sequence listing. Applicant should check the application to ensure that all sequences that meet the requirements of 37 CFR 1.821 comply with the sequence rules' requirement. Appropriate correction is required.

In view of the amendment to the base claims, the following claims are deemed to

be improper dependent claims:

Claim 12 is improper because the claim still recite sequences, e.g., SEQ ID NOS: 35, 7, 54, 74, 87, 113, and 138, wherein each of which is outside of the scope given by the formula as set forth in its base claim 8. Appropriate correction is required.

Claim 66 is improper because the claim still recite sequences, e.g., SEQ ID NOS: 16, 18-20, wherein each of which is outside of the scope given by the formula as set forth in its base claim 8. Appropriate correction is required.

While a new prior art search does not discover any prior art that teaches or suggests SEQ ID NOS: 1, 2, 31, 73, the search has been extended to another species, *e.g.,* SEQ ID NO: 17. As the result, claims readable on SEQ ID NO: 17 are subjected to the following new ground of rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 60, 66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is indefinite in the recitation of "at least about 16 nucleotides" because while the "at least 16 nucleotides" is definite, the "about" does not set forth as to what is exactly the metes and bounds of the "at least". Given that a nucleotide can only be an integer, it is not apparent what is exactly an integer that the "at least about 16" is intended to mean,

particularly if the scope is meant something other than the "16". The recitation of "about 6" in claim 60 is also indefinite for the same reason. In addition, the "PuPy" as recited on the last line of claim 8 does not have a proper antecedent basis. Appropriate correction is required.

Claim 66 is indefinite in the recitation of "not base" or "no base". It is not clear as to the "no base" is supposed to mean. Does applicant intend to mean that X1, for example is not a nucleotide base, then what is it? It is not apparent as to what the negative limitation is intended to mean. Clarification is request.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8, 12-13, 16-22, 60, and 66 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

A substantially pure or isolated oligodeoxynucleotide of at least 16 nucleotides in length comprising a sequence represented by the formula as set forth in claim 8, wherein the oligodeoxynucleotide has a phosphate backbone modification,

does not reasonably provide enablement for any other claimed embodiment. The specification does not enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in In re Wands, 858 F.2d 731, 8USPQ2d 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims embraces therapeutic nucleic acid sequences **comprising** an oligodeoxynucleotide having the formula as set forth in claim 8, wherein the only apparently intended use on the basis of the as-filed specification is to stimulate an immune response in an animal.

A close review of the prior art of record and the as-filed specification indicates that in order to induce any meaningful immune response in an animal model, an administered oligodeoxynucleotide must be modified to have a phosphate backbone modification, whereby such modification would alleviate a rapid degradation of the oligodeoxynucleotide prior to its reaching an intended target tissue or cell. The as-filed specification together with the prior art of record only provide sufficient guidance to reasonably enable claims embracing a phosphate backbone modification. Thus, it is not apparent as to how a skilled artisan, without any undue experimentation, modify by

any other way on the backbone of any immunostimulatory nucleic acid, particularly on the basis of applicant's disclosure.

Thus, given that the lack of understanding as to how to make a CpG DNA without a phosphate backbone modification, which could mediate an immune-stimulatory effect, which is therapeutically effective in an animal model in need of an induction of an immune response, it is not apparent as to how one skilled, without undue experimentation, determines as to which of an enormous number of oligos as embraced by claim 8, can be used as a therapeutic oligo for stimulating an immune response in an immunocompetent animal such as humans.

Claim 8, 16-18, 22 are rejected under 35 USC 102(a) as being anticipated by Mahairas, PNAS, Vol. 17, 9739-9744, 1999. Note that the provisional application 60/128,898, filed April 12, 1999 does not appear to meet the written support for the full scope of claim 8 or the sequence TGCGCCGGCGCAGGGGGG.

The claims are readable on a buffered solution comprising a DNA comprising TGCGCCGGCGCAGGGGGG. Mahairas teaches the same as evidenced by the attached sequence search result, Gene bank database, AN: AQ834558.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8, 12-22, and 60-66 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 09/958,713. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims embrace SEQ ID NO: 1 of this as-filed application or SEQ ID NO: 22 of the copending application and a pharmaceutical composition comprising the sequence.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following prior art is also cited to indicate that claim 8 embraces other sequences disclosed in the prior art: SEQ ID NO: 8 in WO98/38317, NCBI database, AN: A86868, and SEQ ID NO: 36 in US 5756323, NCBI database, AN: AR009571

Applicant's response is moot in view of the new ground of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **571-272-0731**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Amy Nelson*, may be reached at **571-272-0804.**

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Trong Nguyen
Primary Examiner
Art Unit: 1632